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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,318	02/09/2005	Sandrine Bourgeois	L108 1010.1	8669

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EXAMINER	
KOSAR, AARON J	
ART UNIT	**PAPER NUMBER**
1651	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,318	BOURGEOIS ET AL.	
	Examiner	Art Unit	
	Aaron J. Kosar	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-69* is/are pending in the application.

4a) Of the above claim(s) *19-27,37-44,56-58 and 66-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-18,28-36,45-55 and 59-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *2/9/2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/26/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, without traverse, in the reply filed on June 13,2007, is acknowledged.

Claims 19-27, 37-44, 56-58, and 66-69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 13, 2007.

In selecting Group I, Applicant was also required to elect a species (of second active agent) from the group such as those listed in claim 36; however, as the claims are to a device and not limited to the contents within the device (see arguments below), the election of species requirement is *moot*.

Claims 12-18, 28-36, 45-55, and 59-65 are pending and examined on the merits.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on April 26, 2005 has been considered by the examiner. References **F2** and **F4** (EP 0454044 A2 and EP 0273823 A1) are in a foreign language and the specification does not disclose their relevance, thus they have not been considered. Reference **F6** (WO 93/137557) has been considered to the extent of the English abstract.

Specification

The disclosure is objected to because of the following informalities:

The word "cap" appears to be a translation or grammatical error. It is unclear what this word refers to and thus the broadest extent of enablement of the working examples cannot be determined.

Appropriate correction is required.

Claim Objections

Applicant is advised that should **claim 36** be found allowable, **claim 61** will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Should **claim 32** be found allowable, **claim 52** will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 14 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 14 does not require the selection of a macrolide antibiotic (allows for the selection of a quinolone antibiotic), thus claim 14 fails to further limit the claim from which it depends.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed invention is directed to non-statutory subject matter. **Claims 12-14, 28-31, 36, 59-62, and 65** are drawn to a device/composition which may reasonably be interpreted as comprising a product of nature, for example *Escherichia coli*, which inherently produces erythromycin esterase, and is suitable for delivering the enzyme to the colon. Claims 36 and 59 are also drawn to a list of compositions (for example peptides, proteins, genes, etc.) which may be naturally occurring and as presently claimed, do not require isolation, purification, or other manipulation which would free the compositions from naturally occurring materials/products/combinations.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 65 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has reasonably demonstrated/disclosed that the claimed compound is useful as a therapeutic agent for treating symptoms of the exemplified inflammatory bowel disease (IBDs); however, the claims also encompass using the claimed compound to have specificity towards treating colitis and Crohn's disease which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that specificity towards treating Crohn's disease/ulcerative colitis requires a higher standard for enablement than does treating the

symptoms of these disorders, especially since the disorders themselves cannot be totally prevented with current therapies, are incurable, and the causative agents are not yet understood/determined (e.g. see USPATENT APPLICATION 10/347,877,column 1, ¶1,5,and 6).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-18, 28-36, 45-55, 59-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In general, it is clear that a device (an apparatus) can consist of the device itself; however, it is unclear how a device may comprise the device *and* also a second component (an active agent/composition of matter). It is unclear if the invention comprises more than one device. Furthermore, the claims are drawn to an apparatus (a drug delivery device), which is of a different statutory classification of invention than a composition of matter (*e.g.* active agents), thus two invention classifications are proposed single claims though the claims are required to claim only one (class of) invention per claim. One of skill would not be apprised as to the subject matter embraced by the claims and would not be able to determine the metes and bounds of the claims, rendering the claims indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The claims are generally drawn to an apparatus, in particular a drug-delivery device.

It is further noted that the apparatus claims state an intended operation (*e.g.* see claim 12, oral administration and colonic release) and/or the contents during the intended operation (active agent); however as stated in MPEP § 2114 "apparatus claims cover what a device *is*, not what a device does" (*Hewlett-Packard Co. vs. Bausch and Lomb, Inc.*, 909 F.2d 1464,1469, 15 USPQ2d 1525, 1528 (Fed.Cir.1990).

Also, the drug delivery device/apparatus is not reliant on the contents of the apparatus (*e.g.* the pharmaceutical composition/active agent). MPEP § 2115 states, "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims." *In re Young*, 75 F.2d *>996<, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

Though the patentable weight relies upon the device (apparatus). The composition that has also been disclosed has also been considered with respect to the teachings of the prior art, and for the sake of compact prosecution, the rejection under 35 U.S.C. 102(b) below is drawn to the extent of the composition most closely related to the limitations of the apparatus claims.

Claims 12-14, 28-31, 36, 59-62, and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by OLSHENITSKY (USPATENT 6,500,423) as evidenced by ARTHUR (Arthur, M. et al. Annales de l'institut Pasteur, Microbiologie. 137(1.1) Jan/Feb 1986, pages 125-134.) and OUNISSI (Ounissi, H. and Courvalin, P. Gene.1985, 35(3), pages 271-278.).

Olshenitsky teaches a composition comprising an active agent and a drug delivery device. Olshenitsky teaches the drug delivery device suitable for administering the active agent to the colon in teaching an oral/flavor-enhanced probiotic composition for treating the gastrointestinal (GI) tract (Summary ¶1-3, columns 3 and 4). Though Applicant fails to claim the object/subject receiving the drug delivery device, Olshenitsky discloses a device treating a human, and a variety of mammals and avians (column 3, lines 29-44). Olshenitsky also teaches that *Escherichia coli* (and/or the probiotic composition comprising *E. coli*), for example as a food additive or with a flavouring agent (an oral composition), carries the probiotic effect into the GI tract. Olshenitsky further teaches that for conditions treated by antibiotics, probiotics enable the host's gut microflora to return to normal levels (column 1, lines 56-64).

As evidenced by Arthur and Ounissi, *E. coli* and a variety of organisms inherently contain/produce erythromycin esterase (Abstracts).

Thus administering *E.coli* orally to the gut necessarily provides delivery of erythromycin esterase (drug/active agent) to the same GI environment via the bacterial organism (drug delivery device).

With respect to claims 36 and 59, the bacteria and products produced therein anticipates: an antibiotic (E.coli competes against other GI microbes); anti-inflammatory (the composition

treats IBDs); and a peptide/protein/gene/anti-sense oligonucleotide/diagnostic agent/bacteria (*E. coli*, it's structural components, and produced molecules).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-18, 28-36, 45-55, and 59-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over SRIAMORANSAK (**GG**: PTO-1449), MUNJERI (**U**, PTO-892: Munjeri, O., *et al.* Journal of Pharmaceutical Sciences. 1998, 87(8), 905-908.), NOGUCI (Noguchi, N., et al. J. Bacteriology. 2000,182(18),5052-8). and OUNISSI (Ounissi, H. and Courvalin, P. Gene.1985, 35(3), 271-278). Sriamoransak and Munjeri (**U**) teach an active agent, a pectinate bead, which is suitable for colonic release of a variety compounds, including release of protein. Noguci and Ouinissi teach proteins, including isolates of the enzymes erythromycin esterase and macrolide 2'-phosphotransferase I (Mph(A), which are capable of inactivating antibiotics and which are

produced by/isolated from a resident microorganisms native to GI tract flora (including the colon).

Both the active agent and the carrier were known in art. The only difference is the combination of "old elements" into a single composition by enclosing the enzyme with the pectinate bead.

Thus is would have been obvious to one having ordinary skill in the art to admix the pectinate and enzyme, since the *delivery agent* of the active agent is not dependent upon the active agent (the pectinate appears to be generic to the delivery of any compound to the colon, and because the functioning of the active agent is not dependent upon the delivery agent (the delivery agent appears to only interdigitate with the carrier, but does not affect the function of or otherwise interact with the active agent) . Furthermore, the combination of a pectinate with a protein such as erythromycin esterase would have yielded predictable results to a person of ordinary skill in the art at the time of the invention (a composition suitable for delivery to the colon using (a) a colonic delivery pectinate and (b) a protein indigenous to the colon as argued above).

Conclusion

The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

BOUMEESTERS, J.F., et al (USPATENT 6,436,461 as evidenced by WO 98/15192).
Bouwmeesters teaches gel compositions comprising calcium pectinate; the advantages of derivatizing (partially esterified); reticulating a multivalent cation; and using at least one active ingredient (various, Abstract; page 11, ¶ 2; Example 14, figure and lines 12-15).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Kosar whose telephone number is (571) 270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday,EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Aaron Kosar
Examiner, Art Unit 1651

SANDRA E. SAUCIER
PRIMARY EXAMINER